

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

SCHERING CORPORATION,

Plaintiff,

Case number 06-14386

v.

Honorable Julian Abele Cook, Jr.

CARACO PHARMACEUTICAL
LABORATORIES, LTD and SUN
PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

ORDER

This case involves a contention by the Plaintiff, Schering Corporation (“Schering”), that both of the Defendants, Sun Pharmaceutical Industries, Ltd. (“Sun”), and Caraco Pharmaceutical Industries, Ltd. (“Caraco”), infringed upon its ownership rights to U.S. Patent No. 6,100,274 (“the ‘274 patent”), which covers pharmaceutical compositions for the oral administration of a drug commonly known as “desloratadine” and marketed to the general public under the Clarinex trademark. All of these charges have been denied by the Defendants.

I.

Prior to the commencement of this lawsuit, the Sun filed an Abbreviated New Drug Application (“ANDA”) No. 78-539 with the Food and Drug Administration (FDA), seeking to obtain a generic version of Clarinex. All together, fifteen ANDAs¹ were submitted to the FDA by

¹An Abbreviated New Drug Application, or ANDA, is an application that is filed with the FDA for generic drug approval of an existing licensed medication or approved drug. The ANDA contains data, which when submitted to the FDA Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and

or on behalf of twenty-one pharmaceutical entities during mid-2006. According to Schering, each of these ANDAs have sought, and continue to seek, approval from the FDA to produce and sell generic products that contain desloratadine prior to the expiration of its '274 patent. Each application, including Sun's petition to the FDA, contained claims that the '274 patent is invalid and/or would not infringe upon the manufacture or sale of the proposed generic products.

II.

On September 29, 2006, Schering filed a lawsuit in the United States District Court for the District of New Jersey, in which it named all of those corporate entities that had filed ANDAs as defendants, including Sun and Caraco. The following week (October 5, 2006), Schering filed the instant lawsuit in the Eastern District of Michigan against Sun and Caraco. A comparison of these two lawsuits reveals that the allegations in both are substantively identical, with the only major difference being that the New Jersey proceeding involves twenty-one defendants whereas the case in Michigan has only two defendants.

Schering contends that these two lawsuits were filed in an effort to receive the statutory protections to which it is entitled under the "Hatch-Waxman Act."² Under the terms of this legislation, if an original patent owner files a lawsuit suit within forty-five days after receiving notice of an allegedly infringing ANDA, approval by the FDA is automatically delayed for a period of thirty months, or until the court determines that the patent has not been infringed, whichever occurs first. 21 U.S.C. § 355 (c)(3)(c); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677-78

market the generic drug product to provide a low cost alternative to the American public.

²The Drug Price Competition and Patent Term Restoration Act is informally known as the "Hatch-Waxman Act." It is a 1984 federal law which sets forth the process by which potential marketers of generic drugs can file applications for approval with the Food and Drug Administration.

(1990).

Schering acknowledges that it initially filed the lawsuit in New Jersey where it prefers to litigate this dispute. However, Schering submits that, acting upon the concern that the Defendants would challenge personal jurisdiction in New Jersey, it initiated legal proceedings in Michigan.³ On January 8, 2007, Schering filed a motion, in which it asked this Court to stay the proceedings in Michigan to allow the judge in New Jersey to resolve the Defendants' pending jurisdictional challenge.⁴ Sun and Caraco have collectively opposed Schering's request for relief. On March 30th, Schering filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) pursuant to 28 U.S.C. § 1407⁵ which, if granted, would consolidate the New Jersey and Michigan cases. On April 23, 2007, the New Jersey court (1) issued a *sua sponte* order which stayed the case until such time as Schering's motion to consolidate is resolved by the JPML, and (2) denied the Defendants' motion to dismiss without prejudice.

III.

A motion to stay the proceedings is not found in the Federal Rules of Civil Procedure. However, the inherent power of a court to control the disposition of the cases on its docket in an efficient and timely manner includes the authority to stay proceedings. *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). When addressing a party's request for a stay order, a court must exercise its judgment by weighing the competing interests and maintaining an even balance. *Id* at

³The lawsuit in Michigan can be accurately described as a protective measure. According to Schering, it feared that if (1) the Defendants' jurisdictional challenge in New Jersey is successful and (2) the legal proceedings had not been initiated in Michigan, it would have lost the benefit of the thirty month stay of the ANDA that had been filed by the Defendants.

⁴The parties presented oral arguments in support of their respective positions during a hearing on April 10, 2007.

⁵This motion was filed with the JPML on March 30, 2007.

254-55. The party who seeks to obtain a stay must “make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else.” *Id.* at 255. The Sixth Circuit Court of Appeals has also stated that “the burden is on the party seeking the stay to show that there is a pressing need for delay, and that neither the other party nor the public will suffer harm from entry of the order.” *Ohio Envtl. Council v. U.S. District Court*, 565 F.2d 393, 396 (6th Cir. 1977).

Ordinarily, when there is more than one action involving the same patent, the “first to file rule” gives priority to the first lawsuit while the second action is stayed. *Aventis Pharma v. Lupin Ltd.*, 403 F.Supp.2d 484 (E.D. Va. 2005). A district court in the Eastern District of Virginia recently explained that the “‘first to file’ rule applies in two contexts . . . [where] (1) either one patent is involved but there are multiple defendants in different forums, or (2) the defendant files its own ‘mirror-image’ infringement action in another forum in response to being sued.” *Aventis* at 489.

The case law on ANDA litigation is not settled, and there is no definitive guidance to those district courts judges who are charged with handling “protective” lawsuits such as the one at issue here. It is unclear precisely how the “first to file” rule applies in ANDA lawsuits. Thus, in the absence of any definitive guidance, the Court must examine the prejudice, if any, that would be caused to either side from proceeding in this forum or from granting a stay order.

The 1984 “Hatch-Waxman Act” provides a directive to the parties which optimistically states that they “shall reasonably cooperate in expediting the action.” 21 U.S.C. § 3455(c)(3)(c). Here, Schering and the Defendants have accused each other of delaying the proceedings in bad faith and in contravention of the “Hatch-Waxman Act.” While each side has vigorously asserted that the other party is causing an unfair delay in the progression of this litigation, the Court has not received any evidence which supports either position on the issue of bad faith.

IV.

The Defendants contend that they will suffer extreme prejudice if the action in Michigan is stayed. While this lawsuit and the action in New Jersey are pending, Sun's ANDA application is automatically stayed for a period of thirty months or until the cases are resolved, whichever occurs first. Thus, the longer it takes to resolve the dispute in this case, the longer the Defendants will be prevented from producing and potentially profiting from a generic version of Clarinex. However, the recent stay decision by the New Jersey court has made it clear that a final resolution of the dispute over Sun's ANDA will probably not occur in the near future.

Schering maintains that if it is required to litigate identical issues in parallel actions, it will be forced to incur an unwarranted duplication of effort and expense. Noting that there are nineteen other defendants in the New Jersey action, Schering contends that the issues in dispute with all of these challengers are exactly the same which - in the absence of a stay order from this Court - would cause it to expend a substantial amount of its resources to engage in separate discovery in the two jurisdictions. Moreover, Schering asserts that staying this proceeding to allow the New Jersey litigation to move forward expeditiously will conserve judicial resources.

The Court, while genuinely concerned that the finalization of this jurisdictional issue by the New Jersey court may not be soon, finds that it has no other reasonable alternative but to grant Schering's motion for a stay. In rendering this decision, the Court is persuaded that the danger of unfair prejudice to Schering is substantial. In addition, the probable inefficiency and the potential for the misuse of the limited resources of the judiciary that would occur if this litigation moved forward in Michigan while the case in New Jersey was stayed would be significant. Fed.R.Civ.P.

403. As a result, the Court must, and does, grant Schering's motion for a stay. The case is stayed pending a final determination by the JPML regarding consolidation of the cases.

IT IS SO ORDERED.

Dated: June 6, 2007
Detroit, Michigan

s/ Julian Abele Cook, Jr.
JULIAN ABELE COOK, JR.
United States District Court Judge

Certificate of Service

I hereby certify that on June 6, 2007, I electronically filed the foregoing with the Clerk of the Court using the ECF system, and I further certify that I mailed a copy to the non-ECF participant(s).

s/ Kay Alford
Courtroom Deputy Clerk